UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOSEPH M. SULLIVAN, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION et al., Defendants.	HONORABLE JOSEPH E. IRENAS CIVIL ACTION NO. 09-94 (JEI) **OPINION**

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IRENAS, Senior District Judge:

Presently before the Court is the Notice of Removal ("Notice") filed by Defendant Novartis Pharmaceuticals Corporation ("Defendant").[1] The Notice asserts that this action is removable because Plaintiff's New Jersey state law claims "require resolution of issues premised on the application of

[1] The complaint underlying this action also names Novartis Pharma GmbH and Novartis AG as defendants. At oral argument on March 5, 2009, counsel for Defendant stated that neither Novartis Pharma GmbH nor Novartis AG have been served with process in this matter. As used in Part I of this Opinion, the term "Defendants" refers to Novartis Pharmaceuticals Corporation, Novartis Pharma GmbH, and Novartis AG, collectively.

federal law and regulations." This Court, *sua sponte*, issued an Order to Show Cause why the case should not be remanded for lack of subject matter jurisdiction.[2] After considering Defendant's brief in opposition to remand, and having heard oral argument, the Court concludes that the case must be remanded for lack of jurisdiction.

I.

Plaintiff Joseph M. Sullivan filed the instant action on December 8, 2008, in the Superior Court of New Jersey, Law Division, seeking damages for bodily injuries allegedly caused by using Defendants' "Elidel" product to treat his eczema. According to Plaintiff's Complaint, Defendants' conduct in connection with the design, manufacture, distribution, and marketing of Elidel violated the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1, *et seq.*, and common law. The Complaint includes five counts, captioned as follows: (1) NJPLA - Failure to Warn; (2) NJPLA - Defective Design; (3) Breach of Express Warranty; (4) NJPLA - Breach of Implied Warranty; and (5) Punitive Damages Under Common Law and the NJPLA.

On January 8, 2009, Defendant removed the case to this Court, asserting in its Notice that the case arises under federal

[2] The Court has an obligation to raise, *sua sponte*, the issue of its subject matter jurisdiction. *U.S. Express Lines, Ltd. v. Higgins*, 281 F.3d 383, 388-89 (3d Cir. 2002). Pursuant to Fed. R. Civ. P. 12(h)(3), "[i]f the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action."

law, pursuant to 28 U.S.C. § 1331, because the resolution of Plaintiff's NJPLA failure to warn and NJPLA punitive damages claims require the resolution of substantial federal issues. Upon receipt of the Notice, this Court questioned its subject matter jurisdiction, *sua sponte*, and issued an Order to Show Cause why the case should not be remanded.

II.

A.

Pursuant to 28 U.S.C. § 1441(a), "[e]xcept as otherwise expressly provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending." *Liberty Mut. Ins. Co. v. Ward Trucking Corp.*, 48 F.3d 742, 745 (3d Cir. 1995) (quoting 28 U.S.C. § 1441(a)). In cases involving non-diverse parties, "removal is appropriate only if the case falls within the district court's original 'federal question' jurisdiction: 'all civil actions arising under the Constitution, laws, or treaties of the United States.'" *U.S. Express Lines, Ltd. v. Higgins*, 281 F.3d 383, 389 (3d Cir. 2002) (citing 28 U.S.C. §§ 1331, 1441(b); *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 8 (1983)). Under Third Circuit authority, "the party

asserting federal jurisdiction in a removal case bears the burden of showing, at all stages of the litigation, that the case is properly before the federal court." *Frederico v. Home Depot*, 507 F.3d 188, 193 (3d Cir. 2007) (citing *Samuel-Bassett v. KIA Motors Am., Inc.*, 357 F.3d 392, 396 (3d Cir. 2004)).

B.

The content of the plaintiff's "well-pleaded complaint" determines whether an action arises under federal law. *U.S. Express Lines*, 281 F.3d at 389 (citing *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986)). Thus, "a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." *Briones v. Bon Secours Health Sys.*, 69 F.App'x 530, 534 (3d Cir. 2002) (quoting *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987)).[3]

[3] The complete preemption doctrine provides what has alternatively been described as an "independent corollary" or an "exception" to the well-pleaded complaint rule. *See Aetna Health Inc. v. Davila*, 542 U.S. 200, 207 (2004); *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987). The doctrine applies when "the [Supreme] Court has concluded that the pre-emptive force of a statute is so 'extraordinary' that it 'converts an ordinary state common-law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.'" *Kline v. Security Guards, Inc.*, 386 F.3d 246, 252 (3d Cir. 2004) (quoting *Caterpillar*, 482 U.S. at 393). "Once an area of state law has been completely pre-empted, any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law." *Id.* (quoting *Caterpillar*, 482 U.S. at 393). Defendant has not suggested that the doctrine of complete preemption is applicable to the instant case, nor would such an argument be viable. *See Brown v. Organon USA Inc.*, Nos. 07-3092, 07-3456, 08-2021, 2008 WL 2833294, at *2 (D.N.J. Jul. 21, 2008) ("To the Court's knowledge, the complete preemption

Most typically, federal-question jurisdiction "is invoked . . . by plaintiffs pleading a cause of action created by federal law[.]" *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). However, federal "arising under" jurisdiction has long been found over a limited class of state law claims that implicate significant federal issues.[4] *Id.* (citing *Hopkins v. Walker*, 244 U.S. 486, 490-91 (1917)). Thus, in *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), federal courts had jurisdiction over a shareholder's state law action against a corporation, when the dispositive issue was the constitutionality of a federal statute. *Smith*, 255 U.S. at 201. In a recent application of this principle, the Supreme Court held, in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, that arising under jurisdiction extended to a plaintiff's quiet title action under state law that hinged on the interpretation of a federal statute. 545 U.S. 308, 310 (2005).[5]

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doctrine does not apply to the Federal Drug and Cosmetic Act ("FDCA") . . . ."); *In re Aredia and Zometa Prods. Liability Litig.*, No. 3:06-MD-1760, 2007 WL 649266, at *4 (M.D. Tenn. Feb. 27, 2007) (finding that complete preemption does not apply to NJPLA failure to warn or punitive damages claims).

[4] Although the Constitution would permit "arising under" jurisdiction to "extend to all cases in which a federal question is 'an ingredient' of the action," the statutory grant of federal-question jurisdiction is more limited in scope. *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 807 (1986).

[5] For a period of time, the Court's decision in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), created a split among the Courts of Appeals as to whether the existence of a federal private right of action was a condition precedent to the exercise of federal-question jurisdiction over a state law claim. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 311-12, 317 (2005). In *Merrell Dow*, the Court considered whether federal-question jurisdiction extended to a state law claim that included an allegation that a pharmaceutical product was

Grable involved an Internal Revenue Service ("IRS") seizure of real property in satisfaction of a corporation's federal tax delinquency. *Id.* at 310. Pursuant to 26 U.S.C. § 6335, the IRS was required to give notice of the seizure, and it did so via certified mail. *Id.* The corporation did not exercise its statutory right to redeem the seized property, and a buyer purchased the property from the IRS. *Id.* at 310-11. Five years later, the corporation brought a quiet title action in state court, alleging that the buyer's record title was invalid because 26 U.S.C. § 6335 required the IRS to give notice of the seizure via personal service, not certified mail. *Id.* at 311. The buyer removed to federal court, asserting federal-question jurisdiction, because the status of the title turned on whether the IRS effected proper service under the applicable federal statute. *Id.* The Supreme Court granted certiorari solely on the

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"misbranded" in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") because it lacked an adequate warning label. *Merrell Dow*, 478 U.S. at 805-06. Plaintiffs intended to use the FDCA violation as presumptive proof of negligence under state law. *Id.* at 806. The Court explained that Congress had not created or intended a private federal remedy for violations of the FDCA. *Id.* at 810-11. Relying heavily on the absence of a private federal cause of action for the FDCA violation, the Court concluded that the "claimed violation of the [FDCA] as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Id.* at 814.

In *Grable*, the Court clarified that *Merrell Dow* should not be read as "overturning decades of precedent" by "converting a federal cause of action from a sufficient condition for federal-question jurisdiction into a necessary one." *Grable*, 545 U.S. at 317. Instead, the *Merrell Dow* Court had, after "examining the strength of the federal interest at stake and the implications of opening the federal forum, held federal jurisdiction unavailable." *Id.* at 316. *Merrell Dow* "treat[ed] the absence of a federal private right of action as evidence relevant to, but not dispositive of, the 'sensitive judgments about congressional intent' that § 1331 requires." *Id.* at 318.

question of whether the corporation's state law claim was one arising under federal law within the meaning of 28 U.S.C. § 1331. *Id.*

The Court's decision in *Grable* articulated a two-step process to determine whether a state law claim "arises under" federal law under § 1331. *See id.* at 314. First, the state law claim must "necessarily raise a stated federal issue, actually disputed and substantial[.]" *Id.* Second, the federal courts must be able to entertain the state law claim "without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.*

Applying that standard, the Court determined that whether the IRS provided the required notice of the seizure to the corporation was a disputed, essential, and seemingly dispositive element of the quiet title claim. *Id.* at 315. As the Court explained, "[t]he meaning of the federal tax provision is an important issue of federal law that sensibly belongs in a federal court." *Id.* In addition, the case presented the "rare state title case that raises a contested matter of federal law[,]" hence exercising federal jurisdiction would have "only a microscopic effect on the federal-state division of labor." *Id.* Thus, the corporation's quiet title claim was correctly removed as one arising under federal law. *Id.* at 316.

Just one year after *Grable* was decided, the Supreme Court

had occasion to explore the considerations underlying that decision. *See Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699-701 (2006). *Empire Healthchoice* involved an action initiated by a health insurance plan administrator to recover a share of the proceeds from a state court tort suit settlement. *Id.* at 687. The insurer had contracted with the federal government to offer health insurance to federal employees. *Id.* at 682. The contractual arrangement between the federal government and the insurance provider was authorized by the Federal Employees Health Benefits Act of 1959 ("FEHBA"), 5 U.S.C. § 8901, *et seq.* *Empire Healthchoice*, 547 U.S. at 682.

In the case, an insured was injured in an accident, and the insurer expended $157,309 for his care. *Id.* at 687. After the insured's death, his estate received a financial settlement in excess of three million dollars from the parties alleged to have caused his injuries. *Id.* The insurance plan administrator filed suit in federal court seeking reimbursement of the $157,309 spent for the insured's care. *Id.* at 687-88. The estate moved to dismiss on grounds including lack of subject matter jurisdiction. *Id.* at 688. Among other arguments, the insurer contended that federal jurisdiction was proper, under § 1331 and *Grable*, because federal law was an element of its action against the estate. *Id.* at 699.

The Court found federal jurisdiction was lacking; the case

did not fit within "the slim category *Grable* exemplifies." *Id.* at 701. Factors supporting federal jurisdiction in *Grable* included that the case: "centered on the action of a federal agency (IRS) and its compatibility with a federal statute, the question qualified as 'substantial,' and its resolution was both dispositive of the case and would be controlling in numerous other cases." *Id.* at 700 (citing *Grable*, 545 U.S. at 313). *Empire Healthchoice was* "poles apart from *Grable*" because (1) the reimbursement claim was not triggered "by the action of any federal department, agency, or service[;]" (2) the "bottom-line practical issue" was the share of the tort suit settlement properly payable to the insurer; and (3) whereas "*Grable* presented a nearly 'pure issue of law,'" which would bind future courts, the insurer's action was "fact-bound and situation-specific." *Id.* at 700-01.

III.

In this case, Defendant relies on 28 U.S.C. § 1331, as interpreted in *Grable*, as the basis for federal jurisdiction. Specifically, Defendant maintains that Plaintiff's NJPLA punitive damages claim "interject[s] a disputed, necessary, and substantially federal issue into this case[]" and hence the matter is properly before this Court.[6] In addition, Defendant

[6] Defendant's Notice of Removal raised the separate point that Plaintiff's NJPLA failure to warn claim arises under federal law and thus justifies removal. In response to the Order to Show Cause, Defendant pressed solely the NJPLA punitive damages claim as the purported basis for federal

contends that exercising jurisdiction over claims such as this will not disturb the balance of responsibilities between federal and state courts.

Plaintiff's NJPLA punitive damages claim relies on N.J.S.A. § 2A:58C-5(c), which provides in relevant part:

> Punitive damages shall not be awarded if a drug . . . which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," . . . and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. **However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.**

N.J.S.A. 2A:58C-5(c) (emphasis added).

Defendant's argument in support of federal jurisdiction is not a novel one. To the contrary, it is one that has been repeatedly and uniformly rejected. *See Sullivan v. Novartis Pharm. Corp.*, 575 F.Supp.2d 640 (D.N.J. 2008); *Brown v. Organon Int'l Inc.*, Nos. 07-3092, 07-3456, 08-2021, 2008 WL 2833294 (D.N.J. Jul. 21, 2008); *Fields v. Organon USA Inc.*, No. 07-2922, 2007 WL 4365312 (D.N.J. Dec. 12, 2007); *DeAngelo-Shuayto v.*

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jurisdiction. As Defendant has not argued that the NJPLA failure to warn claim provides a sufficient basis for federal-question jurisdiction, the Court expresses no opinion on the merits of such an argument. Notably, another court in this district has rejected the assertion that an NJPLA failure to warn claim presents a federal-question meriting the availability of a federal forum. *See Sullivan v. Novartis Pharm. Corp.*, 575 F.Supp.2d 640, 649-50 (D.N.J. 2008).

Organon USA Inc., No. 07-2923, 2007 WL 4365311 (D.N.J. Dec. 12, 2007); *Von Essen v. C.R. Bard, Inc.*, No. 06-4786, 2007 WL 2086483 (D.N.J. Jun. 18, 2007); *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266 (M.D. Tenn. Feb. 27, 2007). Each of the cited decisions found that the NJPLA punitive damages claim "belong[s] in state court because [its] disposition does not require the resolution of any substantial federal issues, or because a finding of federal jurisdiction would upset the federal-state workload balance." *Sullivan*, 575 F.Supp.2d at 648 (collecting cases).

While acknowledging the existence of those persuasive authorities, Defendant urges this Court to reach a different result. Defendant argues that Plaintiff's affirmative claim for punitive damages relies on proving that Defendant "knowingly misrepresented or withheld material and relevant information required to be submitted under FDA regulations." Defendant maintains that the determination of whether it did, in fact, fail to submit required information to the FDA requires an intricate analysis of the applicable federal statutory and regulatory scheme which should be performed by a federal tribunal.

The Court is not persuaded that this case fits within the "slim category *Grable* exemplifies." *See Empire Healthchoice*, 547 U.S. at 701. Unlike *Grable*, the federal issues embedded in Plaintiff's NJPLA punitive damages claim are not dispositive of

this case or others. Assuming that Defendant's underlying liability is established, it can defend from the assessment of punitive damages by establishing that the relevant language from N.J.S.A. § 2A:58C-5(c) "is preempted and can only be satisfied by an FDA finding of fraud." *Sullivan*, 575 F.Supp.2d at 653.[7] If that preemption defense is successful, the state court will never have occasion to measure Defendant's conduct against the FDA's requirements. *Id.* ("Plaintiffs' claims for punitive damages may not require the New Jersey state court to find fraud-on-the-FDA . . . .").[8]

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[7] As stated above, the possibility of a preemption defense does not give rise to federal-question jurisdiction. *See, e.g., Sullivan v. Novartis Pharm. Corp.*, 575 F.Supp.2d 640, 653 (D.N.J. 2008).

[8] New Jersey's intermediate appellate court recently reversed a jury award of punitive damages upon a finding that N.J.S.A. § 2A:58C-5(c) impinged upon federal statutes and regulations and hence was impliedly preempted. *McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10, 94, 949 A.2d 223 (App. Div. 2008), *certif. granted on other grounds*, 196 N.J. 597, 960 A.2d 393 (2008). In *McDarby*, the jury found in favor of plaintiffs John and Irma McDarby on products liability and consumer fraud claims arising from Merck's distribution of Vioxx. *Id.* at 20, 949 A.2d 223. A component of the verdict in favor of the McDarby's was an award of punitive damages under the NJPLA. *Id.*, 949 A.2d 223. In deciding the punitive damages issue, the jury was permitted to consider a meta-analysis of the incidence of certain heart-related incidents in Vioxx studies. *Id.* at 87-88, 949 A.2d 223. The meta-analysis was conducted in 2000, but not submitted to the FDA. *Id.* at 88, 949 A.2d 223.

Merck appealed, asserting a series of errors, including a claim that the NJPLA punitive damages claim was preempted under the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *McDarby*, 401 N.J. Super. at 88, 949 A.2d 223. *Buckman* involved a series of state law causes of action alleging that a medical device manufacturer made fraudulent representations to the FDA that resulted in orthopedic bone screws receiving market clearance. *Buckman*, 531 U.S. 346-47. The Court explained that "the federal statutory scheme amply empowers the FDA to punish and deter fraud . . . this authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. An implied conflict arose because "[t]he balance sought by the [FDA] can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* The Court held that the state law claims were preempted by the federal scheme. *Id.* at 353.

The Appellate Division agreed with Merck that *Buckman* was controlling

Even if Defendant's preemption defense is unsuccessful, a showing that it "knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question" still is not dispositive of whether punitive damages will be awarded. *See Von Essen*, 2007 WL 2086483 at *5. A showing that a product manufacturer engaged in such misconduct only means that "punitive damages **may** be awarded." N.J.S.A. § 2A:58-5(c) (emphasis added). Plaintiffs would still be required to demonstrate the propriety of punitive damages based on a series of factors defined by state law. *Von Essen*, 2007 WL 2086483 at *5 (citing N.J.S.A. § 2A:15-5.12).

Moreover, in contrast to *Grable*, where the facts were undisputed and only the meaning of a federal tax statute was at issue, there is no indication, at present, that this case "depend[s] on the construction or interpretation of federal law."

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authority for the proposition that the McDarby's NJPLA punitive damages claim, conditioned on establishing a knowing misrepresentation by Merck to the FDA, was impliedly preempted by the FDA's regulatory scheme. *McDarby*, 401 N.J. Super. at 94, 949 A.2d 223. Thus, the Appellate Division reversed the jury's award of punitive damages. *Id.*, 949 A.2d 223.

The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, 555 U.S. ____ (2009). In *Levine*, the Court held that a state tort suit alleging that a pharmaceutical company's failure to provide an adequate warning on an ethical drug was not preempted. *Id.* at *2, 555 U.S. ____. In so holding, the Court determined that the imposition of state tort duties did not pose an obstacle to the sound operation of the federal drug labeling regulations. *Id.* at *10, 555 U.S. ____. The Court could discern no Congressional intent to vest the FDA with the sole authority to ensure drug safety and effectiveness, as would result from the preemption of state tort actions. *Id.*, 555 U.S. ____.

Brown, 2008 WL 2833294, at *4. Defendant responds that the progression of this case may reveal a latent dispute as to what information it was required to submit under FDA regulations. In other words, Defendant contends that this case may involve embedded issues requiring this Court to perform a legal inquiry into the meaning of one or more FDA regulations.

At present, there is nothing before the Court to suggest that this case will present the legal issues of regulatory interpretation predicted by Defendant. To the contrary, all indications are that the federal aspect of the NJPLA punitive damages claim will depend on a fact-sensitive inquiry into whether material information concerning Elidel was knowingly withheld from, or misrepresented to, the FDA. In the absence of any current indication that this case will require the resolution of disputed federal issues of general application, *Grable* counsels against the exercise of jurisdiction.

As additional evidence of the substantial federal interests purportedly at stake, Defendant relies on the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *Buckman* involved state law claims that a medical device manufacturer made misrepresentations to the FDA that resulted in orthopedic bone screws receiving market clearance. *Buckman*, 531 U.S. at 346-47. Plaintiffs sought damages, claiming that "but for" the misrepresentations to the FDA, the bone screws

never would have reached the market. *Id.* at 343. The Court held that plaintiffs' claims conflicted with, and hence were impliedly preempted by, the FDCA, as amended by the Medical Device Amendments of 1976 ("MDA"). *Id.* at 343, 348.

As various courts have recognized, *Buckman*'s holding rested on principles of implied preemption; the case did not "make any holding with regard to the existence of federal-question jurisdiction over a case by virtue of a state law claim that incorporates federal law as setting forth the standard of offending conduct." *Sullivan*, 575 F.Supp.2d at 651 (internal quotes omitted); *Brown*, 2008 WL 2833294, at *4; *Fields*, 2007 WL 4365312, at *7. The issue before this Court "is whether [Plaintiff's] claim[] arise[s] under federal law, not whether there is preemption under *Buckman*." *Sullivan*, 575 F.Supp.2d at 651. Moreover, "*Buckman* involved a specific cause of action for fraud-on-the-FDA, whereas the instant [Plaintiff] must prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under New Jersey law." *Id.* at 652.

Further, unlike the instant case, *Buckman* was decided under the auspices of the MDA. Federal medical device regulation has, since its inception, provided for the preemption of conflicting state requirements via an express preemption clause. *See* 21 U.S.C. § 360k. That preemption clause reflects a legislative prerogative to displace certain state causes of action in the

realm of medical devices.[9] By contrast, the ethical drug arena is one in which state tort liability and federal regulation have traditionally operated in parallel, in a scheme implicitly approved by Congress. *See Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at *10, 555 U.S. _____ (2009) ("[Congress'] silence on the issue [of preemption], coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."). Particularly given these historical differences between the areas of medical devices and pharmaceuticals, the Court is not persuaded by Defendant's reliance on *Buckman* as evidence of a substantial federal interest in the case at bar.

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[9] Under the MDA, the most heavily regulated medical devices, known as "Class III" devices, can reach the market via either of two paths—full premarket approval ("PMA") or the significantly less intensive "section 510(k)" process. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1003-04 (2008). Under the § 510(k) process, an applicant need show only that the device seeking FDA approval is "substantially equivalent" to a medical device that was on the market prior to the enactment of the MDA. *Id.* at 1004. By contrast, PMA applicants undertake a rigorous process that includes extensive FDA scrutiny. *Id.*

In 1996, the Supreme Court determined that § 360k does not preempt common law negligence and strict liability claims alleging injuries caused by a medical device authorized for marketing via the § 510(k) process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 404, 502 (1996). By contrast, common law claims alleging injuries from a medical device approved via the PMA process are expressly preempted by § 360k, unless the state duties merely parallel federal requirements. *Riegel*, 128 S. Ct. at 1011. *Buckman* was decided in the interim between *Lohr* and *Riegel*, and declined to consider whether the fraud-on-the-FDA claims were expressly preempted under the MDA, instead finding the claims were impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 348 n.2 (2001). Interestingly, the *Buckman* plaintiffs likely crafted their fraud-on-the-FDA causes of action in hopes of avoiding the operation of the MDA's express preemption provision.

Finally, Defendant argues that its position is supported by the FDA's comments in conjunction with the dissemination of a Final Rule amending the regulations governing pharmaceutical labeling. *See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006). Therein, the FDA expressed concern that state law actions could propagate interpretations of FDA regulations that conflict with the agency's own interpretations, thereby frustrating the FDA's ability to regulate. *Id.* at 3934.

Defendant's reliance on the FDA's remarks is misplaced. That the FDA has an interest in the uniform interpretation and application of its regulations does not require federal-question jurisdiction to extend to this action. A statement by the Supreme Court in *Merrell Dow* applies with equal force to Defendant's argument in the instant case:

> To the extent that [Defendant] is arguing that state use and interpretation of the FDCA pose a threat to the order and stability of the FDCA regime, [Defendant] should be arguing, not that federal courts should be able to review and enforce state FDCA-based causes of action as an aspect of federal-question jurisdiction, but that the FDCA pre-empts state-court jurisdiction over the issue in dispute.

Merrell Dow, 478 U.S. at 816.[10]

[10] Reliance on these comments by the FDA has failed even in the preemption context. In *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, 555 U.S. ____ (2009), a pharmaceutical company attempted to rely on the FDA's remarks as evidence that state law failure to warn claims "would obstruct the purposes and objectives of federal drug labeling regulation." *Id.* at *10, 555 U.S.

In sum, the Court finds that this case is not one "that necessarily raise[s] a stated federal issue, actually disputed and substantial" meriting access to the federal forum. As Defendant has not carried its burden to show that this case is properly before this Court, it must be remanded.

In the alternative, even if Plaintiff's NJPLA punitive damages claim presented sufficiently substantial federal issues, jurisdiction still would not be appropriate in light of the "potentially enormous shift of traditionally state cases into federal courts" that would follow. *Sullivan*, 575 F.Supp.2d at 653 (quoting *Grable*, 545 U.S. at 319). Some cases might require courts to postulate whether the anticipated shift of cases from state courts to the federal system is real or merely conjectural. This is not such a case. Here, there is ample proof that federal jurisdiction over NJPLA punitive damages claims would markedly increase the volume of such cases in federal courts. *Brown v. Organon International Inc.* was a consolidated decision which rejected N.J.S.A. § 2A:58C-5(c) as the basis for federal-question jurisdiction and remanded fifty-four actions against a pharmaceutical company to state courts. *Brown*, 2008 WL 2833294, at *4-*5. Nineteen actions similar to the instant case are

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____. The Court wholly rejected the company's argument, finding that the FDA's remarks did not merit any deference for a variety of reasons, including the agency's failure to "offer[] States or other interested parties notice or opportunity for comment" before articulating its "sweeping position[.]" *Id.* at *11, 555 U.S. _____. In addition, the Court determined that the FDA's position was contrary to that of Congress. *Id.* at *10, 555 U.S. _____.

currently pending in the Camden vicinage of the District of New Jersey. Like Judge Debevoise, this Court can discern no congressional intent to open the federal courts to the mass of state actions involving ethical drugs seeking punitive damages under the NJPLA. *See Sullivan*, 575 F.Supp.2d at 653.

IV.

In closing, the Court emphasizes that N.J.S.A. § 2A:58C-5(c) is a cause of action for punitive damages, not one for fraud-on-the-FDA. A showing of fraud-on-the-FDA is simply a gateway, through which plaintiffs must pass before pursuing punitive damages. Ultimately, it is a substantial body of New Jersey law that determines when a jury may award punitive damages.

For the reasons stated above, this Court lacks subject matter jurisdiction over the present case. This action will be remanded to the Superior Court of New Jersey, Law Division. The Court will issue an appropriate Order.

Dated: March 6, 2009

s/ Joseph E. Irenas
JOSEPH E. IRENAS, S.U.S.D.J.